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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,821	12/31/2003	Robert E. Burgmeier	S63.2-11032-US01	9361
490 7590 07/02/2007 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER HUSON, MONICA ANNE	
			ART UNIT 1732	PAPER NUMBER
			MAIL DATE 07/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/749,821

Applicant(s)

BURGMEIER ET AL.

Examiner

Monica A. Huson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 and 24-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 031804,072005,072805.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

This office action is in response to the Telephone Election 15 May 2007.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1-19 and 24-30, drawn to a medical device part, classified in class 428, subclass 35.7.

Claims 20-23, drawn to method of forming a polymeric part, classified in class 264, subclass 211.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as casting or compression molding a polymeric material in the form of a polymeric part.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Walter Steinkraus on May 15, 2007 a provisional election was made with traverse to prosecute the invention of Group II, claims 20-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-19 and 24-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Claim Objections

Claim 20 is objected to because of the following informalities: It is believed that the phrase --at least one of-- is missing in line 14 of claim 20, between the words "and" and "the". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (U.S. Patent 6,596,2960, in view of Katayama et al. (U.S. Patent 6,552,123). Regarding Claim 20, Nelson et al., hereafter "Nelson," show that it is known to carry out a method of forming a polymeric part for a medical device comprising passing a mass of molten polymer material composition to form an emitted mass (Column 18, lines 12-13), subsequently cooling the emitted mass, without substantially mixing the emitted mass material, whereby the cooled emitted mass comprises at least two regions of material located within the cooled mass in a fixed relationship to each other, said fixed relationship corresponding substantially to the sequence of emission of the polymer material forming each said region (Column 3, lines 51-65; Column 18, lines 36-40; Column 19, lines 52-60), wherein the method further comprises varying an amount of polymer modifier in the polymer composition passing through said opening between the emission of the material forming the first region and the emission of the material forming the second region, whereby at least one of the two regions is provided with a positive amount of the polymer modifier and [at least one of] the two regions are provided with differing amounts of the polymer modifier (Column 2, lines 45-48; Column 3, lines 51-65; Column 19, lines 48-55). Nelson does not show using a crystallization modifier as the polymer modifier. Katayama et al., hereafter "Katayama," show that it is known to carry out a method wherein a crystallization modifier is used during a polymeric extrusion operation (Column 10, lines 9-16). Katayama and Nelson are combinable because they are concerned with a similar technical field, namely, methods of extruding polymeric articles. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Katayama's crystallization modifier as the polymeric modifier in Nelson's molding process in

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order to avoid premature crystallization of the polymer, and thus, cause problems in the molding or post-forming steps.

Regarding Claim 21, Nelson shows the process as claimed as discussed in the rejection of Claim 20 above, including a method wherein the amount of the polymer modifier is varied within the range of 0 to about 20 wt% (Figure 6, 9A). Nelson does not show using a crystallization modifier as the polymer modifier. Katayama shows that it is known to carry out a method wherein a crystallization modifier is used during a polymeric extrusion operation (Column 10, lines 9-16). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Katayama's crystallization modifier as the polymeric modifier in Nelson's molding process in order to avoid premature crystallization of the polymer, and thus, cause problems in the molding or post-forming steps.

Regarding Claim 22, Nelson shows the process as claimed as discussed in the rejection of Claim 20 above, including a method wherein the passing step comprises extruding the molten polymer through a die head (Column 18, lines 12-13), meeting applicant's claim.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson and Katayama, further in view of Gahara et al. (U.S. Patent 4,950,239). Nelson shows the process as claimed as discussed in the rejection of Claim 20 above, but he does not show using injection molding to form his product. Gahara et al., hereafter "Gahara," shows that it is known to carry out a method of forming an elongated product using injection molding (Column 5, lines 16-18). Gahara and Nelson are combinable because they are concerned with a similar technical field, namely, methods of molding long, thin objects. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Gahara's injection molding as the formation step of Nelson's process in order to form objects of precisely the same size, instead of extruding an infinite article and requiring a cutting operation thereafter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A. Huson whose telephone number is 571-272-1198. The examiner can normally be reached on Monday-Friday 7:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Monica A. Huson". The signature is fluid and cursive, with the first name "Monica" being more prominent and the last name "Huson" following in a similar style.

Monica A Huson

June 20, 2007